DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Re: Humira
Docket No.: 2004E-0445

JAN - 6 2006

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 6,090,382, filed by Abbott Biotechnology Ltd., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Humira, the human biological product claimed by the patent.

The total length of the regulatory review period for Humira is 1,722 days. Of this time, 1,443 days occurred during the testing phase and 279 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this biologic product became effective: April 16, 1998.

   FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 16, 1998.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act: March 28, 2002.

   FDA has verified the applicant's claim that the product license application (BLA) for Humira (BLA 125057) was initially submitted on March 28, 2002.

3. The date the application was approved: December 31, 2002.

   FDA has verified the applicant's claim that BLA 125057 was approved on December 31, 2002.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Steven Weinstock
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